

# **EXHIBIT**

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**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

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**IN RE: ETHICON, INC. PELVIC SYSTEM  
PRODUCTS LIABILITY LITIGATION**

**Master File No. 2:12-MD-02327**

**MDL 2327**

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**THIS DOCUMENT RELATES TO:**  
*Rosa Crawford v. Ethicon, Inc., et al.*  
*2:12-cv-6181*

**HON. JOSEPH R. GOODWIN**

**RULE 26 EXPERT REPORT OF DR. WILLIAM PORTER, M.D.**

**A. Qualifications and Background.**

My name is William Edward Porter, M.D. I received a bachelor's degree in biology at the University of Michigan located in Ann Arbor, MI. I then went on and obtained a medical degree from the Wayne State University located in Detroit, MI. I subsequently completed a residency in obstetrics and gynecology at the University of Cincinnati and an American Board of Obstetrics and Gynecology certified three-year fellowship in Female Pelvic Medicine and Reconstructive Surgery (FPMRS) at the University of Tennessee Medical Center located in Memphis, Tennessee. I am one of the first ABOG Certified Physicians in the United States in the Field of (FPMRS). I served as a reviewer for the International Urogynecology Journal (2003 to 2006). I am currently a journal reviewer for Female Pelvic Medicine & Reconstructive Surgery. I serve on the American Urogynecology Society Coding Committee (2012 to 2016). I have lectured locally, nationally, and internationally on many subjects in the field of urogynecology and reconstructive pelvic surgery, including pelvic organ prolapse and urinary incontinence. I have taught at many medical device industry sponsored labs, the purpose of which has been to instruct other surgeons on the proper use of surgical devices and tools to treat pelvic organ prolapse and stress incontinence. I have also worked as a consultant to many medical device companies in developing and validating new products in the pelvic floor space.

I am trained extensively and practice exclusively in the field of pelvic medicine. This field encompasses pelvic organ prolapse, urinary incontinence, fecal incontinence, pelvic pain and pelvic floor dysfunction. Over the past 14 years post residency, I have performed nearly 3,000

pubovaginal slings (synthetic and xenographic) and fascia latta bladder neck slings. I have performed several thousand vaginal repairs for pelvic organ prolapse using native tissue, allograph, xenograph or synthetic augmented repairs. In the same regard I have also removed slings and mesh complicated surgeries (erosion and/ extrusion).

I have been specifically trained to use pelvic organ products (slings, graphs and mesh kits) by the following companies: C. R. Bard, Boston Scientific, Mentor, Cook Medical, Gynecare, American Medical System and Coloplast. I did complete any training required by said companies. I have been a trained proctor for the following companies: C.R. Bard, Boston Scientific, Mentor, Cook Medical, Gynecare and Coloplast. I have specifically treated female patients with the GYNEMESH PS.

Based upon my work as a urogynecologist (FPMRS), I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants and mid-urethral slings. The focus of my evaluation is the role that the GYNEMESH PS meshes played in causing injury to Ms. Crawford. The most common mesh-related complications are pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation of tissue, chronic vaginal discharge or bleeding, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion of mesh into tissues or organs, and nerve entrapment. In diagnosing and treating patients with mesh related complications, I often determine the likely cause of the patient's complications based upon a differential diagnosis, which typically includes a physical and history and a review of her medical records and other information about the patient.

In formulating the opinions set forth in this report I have relied on my personal knowledge, education and training, prior experience in treating stress urinary incontinence, medical literature, and a review of relevant medical records pertaining to Ms. Crawford. All of my opinions are true and correct to the best of my knowledge. I do reserve the right to supplement this report and my opinions if additional information becomes available (reports, discovery, articles or other relevant information). I also reserve the right to perform a physical examination on Ms. Crawford.

## **B. Summary of Materials Reviewed**

I have reviewed the following medical records and depositions with accompanying exhibits pertaining to Rosa Crawford:

Fairview Lakes Regional Medical Center

Fairview Rush City Clinic

Metro Urology

Allina Health

Abbott Northwestern

Cambridge Medical Center

Deposition of Rosa Crawford

Plaintiff Profile Form and Plaintiff Fact Sheet of Rosa Crawford

**C. Summary of Medical Facts related to Rosa Crawford**

**DOB: 12/24/1963**

**Past Medical History:**

Chronic Neck Pain, Alcoholism, Depression, PTSD (neck), Fibromyalgia

**Past Surgical History:**

Posterior Spinal Fusion, Anterior Spinal Dissectomy, tubal Ligation, Anterior Repair with GYNEMESH, Laser Eye Surgery

**Medications:**

ProAir, Tramadol, Lunesta, Wellbutrin

**Social:**

+ Tobacco

11/7/2003

She has a Stage 2 Cystocele and a small rectocele and uterus reasonably suspended.

2/26/2004

She had urodynamics. She a large bladder capacity and Intrinsic Sphincter Capacity.

3/30/2004

She had an anterior repair with Gynemesh PS mesh, posterior repair with Gynemesh PS mesh, and IVS sling for urinary incontinence.

5/7/2004

She is 6 weeks postop surgery. She reports some pain with defecation

9/26/2005

Abdominal ultrasound for pain. Normal.

6/1/2006

She was diagnosed with mesh exposure.

6/21/2006

She reports a vaginal ridge with pain with tampon insertion. Her partner felt mesh with coitus. The mesh was exposed with a dime-sized extrusion of the mesh at the apex of the vagina under the bladder. This was excised ( Dr Chuck Huckabay)

2007

Menorrhagia she had an endometrial ablation.

1/15/2009

She had routine Gynecology visit.

11/4/2009

She reports pain in the vagina and anus. She feels that she has mesh in the colon and constipation.

4/6/2010

She was seen by Suzette Sutherland. She reports 2 office mesh trimmings. She reports pain with coitus postoperatively. She has had 2 UTIs. She denies any stress incontinence. She has some frequency. She had exposed mesh that is palpable just in front of the cervix at the anterior vaginal wall. No pain along the sling.

5/12/2010

Exposed Vaginal Mesh: She had exposed mesh. She had continued spotting and discharge. She had continued exposure at the top of vaginal canal near cervix. Pathology 1.5x1.5x0.5.

7/8/2010

She is postoperative of 3 cm mesh removal. She had used excessive vaginal estrogen postoperatively. She denies any vaginal symptoms.

2/27/2012

She had a normal pelvic examination



## Deposition

She feels the mesh keeps coming out her vaginal walls. She reports her husband feels something with coitus.

### **D. Methodology and Analysis.**

In determining the cause of a specific injury, it is customary to “rule in” potential causes of the injury, and then by process of elimination, to “rule out” the least likely causes to arrive at the most likely cause. This process is known as differential diagnosis, or differential etiology, and it is a well-established and universally accepted methodology for determining the cause of injuries employed by physicians throughout the United States. I often determine the cause of a patient’s complications based upon an interview with the patient, a review of her medical records or knowledge of her prior medical history. I have used that methodology in arriving at my opinions in the case.

During her visits she reports having dyspareunia that prevented her from coitus. Meyer et al reports dyspareunia rates of 36% at a 5 year follow up from mesh surgery. On the other hand, Alperin et al reports a dyspareunia rate of 28.9%, which was similar to preoperative rate. Porter et al reports a site-specific posterior repair tends to have a positive effect on dyspareunia 73% cured vs. 19% where it increased.

As the vagina is a cleaned contaminated area, there is no way to completely eliminate bacteria from the surgical site. Implantation though this dirty field could allow bacteria to attach. These bacteria then can attach to the mesh and secrete a biofilm or a polysaccharide slime excreted by the bacteria. This slime could prevent the host defensive mechanism from clearing the infection. (Edmiston). This tissue response can contribute to the cause of vaginal pain, pelvic pain and chronic inflammation. This chronic inflammation/infection could be a source of pain. This chronic inflammation/infection could be a source of an erosion, vaginal discharge and possible UTI’s. Dr. Daniel Elliott in his general expert report suggested the mesh creates a foreign body reaction and a chronic inflammatory response that can lead to chronic pain in the patient. The body’s foreign body response to the mesh can cause a severe and chronic inflammatory reaction leading to excessive scarring in and around the mesh. Dr. Bruce Rosenzweig of the general expert witness group suggests that mesh degrades over time and causes a chronic foreign body reaction, fibrotic bridging, mesh contracture/shrinkage, fraying, particle loss, roping and curling of the mesh contributing to pain. Ethicon’s Daniel Burkley, a Principal Scientist has testified that polypropylene mesh in human beings is subject to some degree of surface degradation

In considering the cause of the pain, dyspareunia, mesh erosion and chronic UTIs suffered by Rosa Crawford, her GYNEMESH PS meshes contributed to her pain and mesh erosions. This is from what Dr Rosenzweig’s refers as a chronic inflammation from the mesh causing a contraction and subsequent mesh exposure.

The next step in my analysis was to rule out other potential causes. I did consider other potential causes including post-op scarring and granulation tissue from her tubal ligation, hysterectomy, prolapse surgery and bladder surgery. I also considered other factors in her history including her previous pelvic surgery and sling. She currently has the following

problems: Chronic Neck Pain, Alcoholism, Depression, PTSD (neck), Fibromyalgia. I considered each of these other risks for her pain, dyspareunia, mesh erosion, and I concluded that they could be ruled out as a source of her pain, dyspareunia, mesh erosion suffered by Rosa Crawford.

Additionally, it is my opinion to a reasonable degree of medical and scientific certainty, based on my background, education, training and experience, that Rosa Crawford's treating physicians who implanted her pelvic mesh met the standard of care during implantation of the devices. I found no evidence of surgical error or deviation from the requisite procedural steps. Further, after reviewing the operative reports, I see no evidence of any surgical complications.

#### **E. Conclusion.**

Based on the foregoing analysis, and based on my education, training and knowledge, it is my opinion to a reasonable degree of medical probability that the cause of Ms. Crawford's dyspareunia, pain and mesh erosions is related to her GYNEMESH Mesh Implant. This issue is related to what Dr Elliott described as a chronic inflammation around the mesh. As per Dr. Klinge opinion of Ethicon's designed is that it causes a greater than necessary inflammation and foreign body reaction as is occurring in Ms. Crawford. This continued inflammation prevents the would from healing and propagating a continued mesh exposure and pain.

#### **XXI.**

I have the right to supplement and amend this opinion should additional factual information be forwarded to me that I did not have available at the time this opinion is submitted.

Dated this the 22<sup>th</sup> day of May, 2017

A handwritten signature in dark ink, appearing to read "William Porter", with a long horizontal flourish extending to the right.

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William Porter, M.D.